K133855

510(k) Summary

JAN 31 2014

Device **Breezy Elegance Manual Folding Wheelchair**

Owner

Sunrise Medical (US) LLC
2842 Business Park Avenue
Fresno, CA 93727
Phone: 559-348-2572
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Contact

Laurie H. Roberts
Senior Manager—Regulatory Affairs

Date 17 December 2013

Subject Device

Trade name	**Breezy Elegance**
Common name	**Manual Folding Wheelchair**
Regulation	**21 CFR 890.3850**
Device name	**Mechanical wheelchair**
Product code	**IOR**
Device class	**1**
Panel	**Physical Medicine**

Predicate

Trade name	**Quickie Q2 Lite**
Manufacturer	**Sunrise Medical (US) LLC**
Market Clearance	**510(k): K072153 (10 Sep 07)**

Device Description

Device purpose The product offering consists of a standard folding aluminum wheelchair. (Standard in the sense that it is not built to a specific order, rather it will be built to inventory.)

Device components

- The wheelchairs are
  - User-propelled, as such, chair has 24" wheels with attached handrims
  - Foldable (using a cross-brace design) for easier transport and stowage

Continued on next page

Device components (continued)	• The device comprises - Cross-braced folding frame - Quick-release Axle - Large rear wheels with handrims for self-propulsion - Smaller front wheels on casters for stability - Padded seat sling material designed to support a seat cushion and to fold when the wheelchair frame is folded - An upholstered backrest designed to fold when the wheelchair frame is folded, pre-set angle to 8° - Push handles at top of backrest to allow attendant to aid mobility of rider - Swing-away armrests and swing-in/swing-out legrests (with footplates) • Available Options Elevating legrest Anti-tip Tubes
Technological characteristics	• Aluminum frame to reduce weight and provide durability • Triple cross-brace for easy folding • Swing-away arm and leg rests for easier entry, egress, or transfer • Seat and back slings to accommodate separate cushion system for rider comfort and ease of folding • Tension adjustable back straps for user comfort • Optional on Models B & C - Drum brake system to aid attendant to control chair movement - Height adjustable push handles for attendant comfort - Height adjustable armrests for user comfort

Intended Use

Breezy Elegance Folding Manual Wheelchairs are manually operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position.

Equivalence

The Breezy Elegance Wheelchair is substantially equivalent to its predicate device, Quickie Q2 Lite, based on intended use, materials, operating principle, technology, safety, and performance.

Breezy Elegance equivalence to Quickie Q2 Lite

Intended Use	Identical: Provides mobility to persons restricted to a sitting position

Materials	Substantially equivalent: • Aluminum frame, support members, wheels, and components • Steel fasteners and components • Flexible polymeric tires • Fabric covered foam upholstery • Fabric straps and slings
Operating principle	Identical: • User propelled by hand pressure against handrims attached to large (24 inch) wheels • Wheel locks to hold chair on slight slopes • Quick release wheel hubs for easy removal of wheel for transport and storage • Cross-braced, hinged frame for folding of chair for transport and storage • Seat cushion and back upholstery for user comfort • Adjustable, swing-away legrests with angle-adjustable footrests • Push handles to allow assistance by an attendant
Energy source	Identical: User propelled
Technology	Identical: Standard mechanical wheelchair construction and operation.
Safety and performance	Substantially equivalent: • Accomplishes the same performance in the same way as the predicate with slightly more weight and weight carrying capacity • Design raises no new issues of safety or effectiveness

Bench Tests

Design Verification	Design Control requirements per 21 CFR 820.30; testing/demonstration that all essential specifications show equivalent performance to recognized wheelchair standards or to the predicate device (Quickie Q2 Lite).
Design Validation	Third-party evaluation of chair performance, human factors, and usability demonstrate the fitness of the design to meet the requirements and demands of its intended use.

Biocompatibility

Type of Contact	• Momentary contact with uncompromised skin of hands—various parts • Transient contact with uncompromised skin of hands—handrims • Transient contact with uncompromised skin of arms—armrests
Evaluation	• Momentary contact of intact skin of hands on aluminum, steel, nylon fabric, hard/soft plastics do not raise biocompatibility issues • Handrim and armrest materials are identical with the predicate device and, thus, raise no biocompatibility issue

Packaging / Shelf life

Based on the durability, materials, and use of wheelchairs, packaging and shelf life are not relevant to the safe and effective use of these devices.

Conclusion

Breezy Elegance Manual Folding Wheelchairs are substantially equivalent to their predicate devices in technology, performance, and intended use. There are no significant differences between Breezy Elegance Wheelchairs and the Quickie Q2 Lite Wheelchair predicates in design which would raise new issues of safety and effectiveness, performance, function or intended use of the device. In addition, the chair design has been shown to be safe and effective for its intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

Sunrise Medical (US) LLC
c/o Laurie H. Roberts
2842 Business Park Ave.
Fresno, CA 93727

Re: K133855
Trade/Device Name: Breezy Elegance Folding Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 2, 2014
Received: January 2, 2014

Dear Ms. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133855

Device Name
Breezy Elegance Folding Manual Wheelchair

Indications for Use *(Describe)*
Breezy Elegance Folding Manual Wheelchairs are manually operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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